MAiN
Managing Abstinence in Newborns

FRAMING:
BUILDING A SUBSTANCE EXPOSURE PROGRAM FOR NEWBORNS

SC Birth Outcomes Initiative Symposium
November 16, 2017

Jennifer A. Hudson, MD
Michelle Greco, RNC, BSN

INTRODUCTION

- MAiN Program Administrators
  - Medical Director
    - Jennifer Hudson
  - Project Manager
    - Michelle Greco

DISCLOSURES

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- The presenters have no significant financial or commercial interests to disclose.
- Today's discussion will include the use of oral methadone solution to prevent and treat neonatal opioid withdrawal, which is an "off-label" use. There are no FDA-approved medications for treating withdrawal in children, but the American Academy of Pediatrics supports the use of oral methadone and morphine solutions for this purpose.
- This presentation is for educational purposes only. No portion may be video taped or reproduced for future distribution or presentation without the express consent of the presenters.

OBJECTIVES

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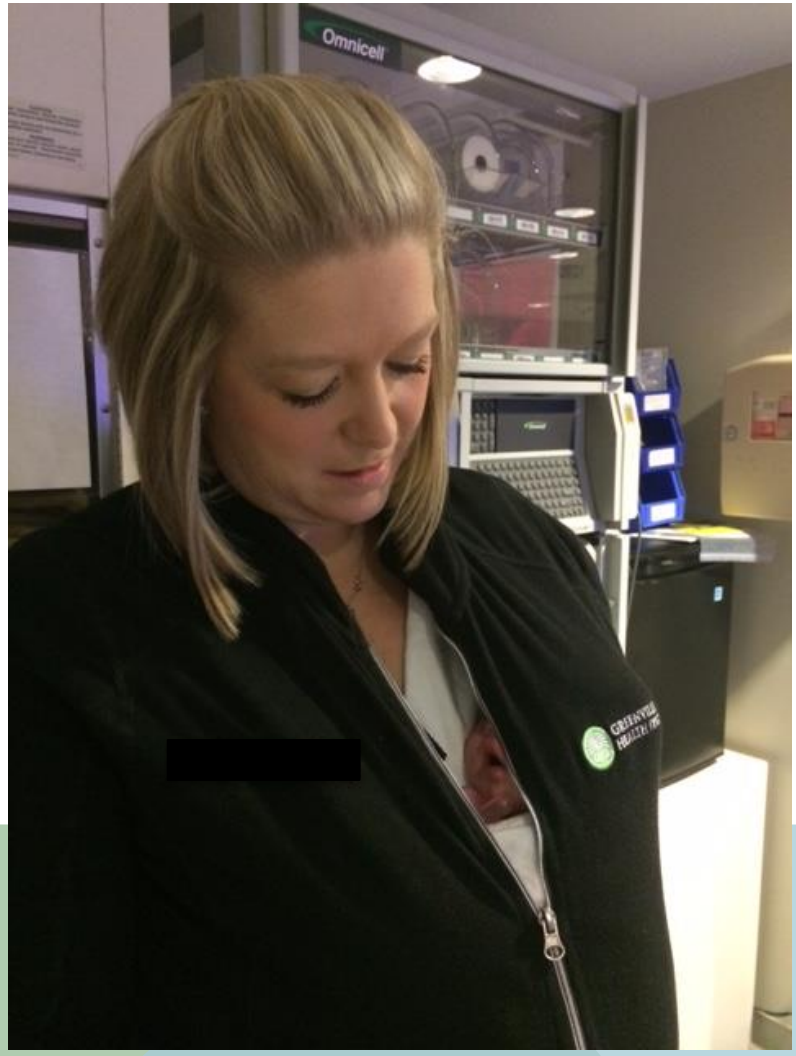
- Understand the **case for need** behind MAiN expansion
- Assess your facility's **readiness** for implementing the MAiN model
- Recall the **benefits and steps** for applying to become a MAiN-designated facility

SESSION AGENDA

- Framing the Issue
- The MAiN Model
  - Overview
  - Cohort Analysis
  - Outcomes
- MAiN Expansion
  - AnMed
  - Grant Overview and Timeline
  - Resources
  - Expectations
  - Application Process and Timeline
  - Next Steps
- Questions

WHY WE'RE HERE



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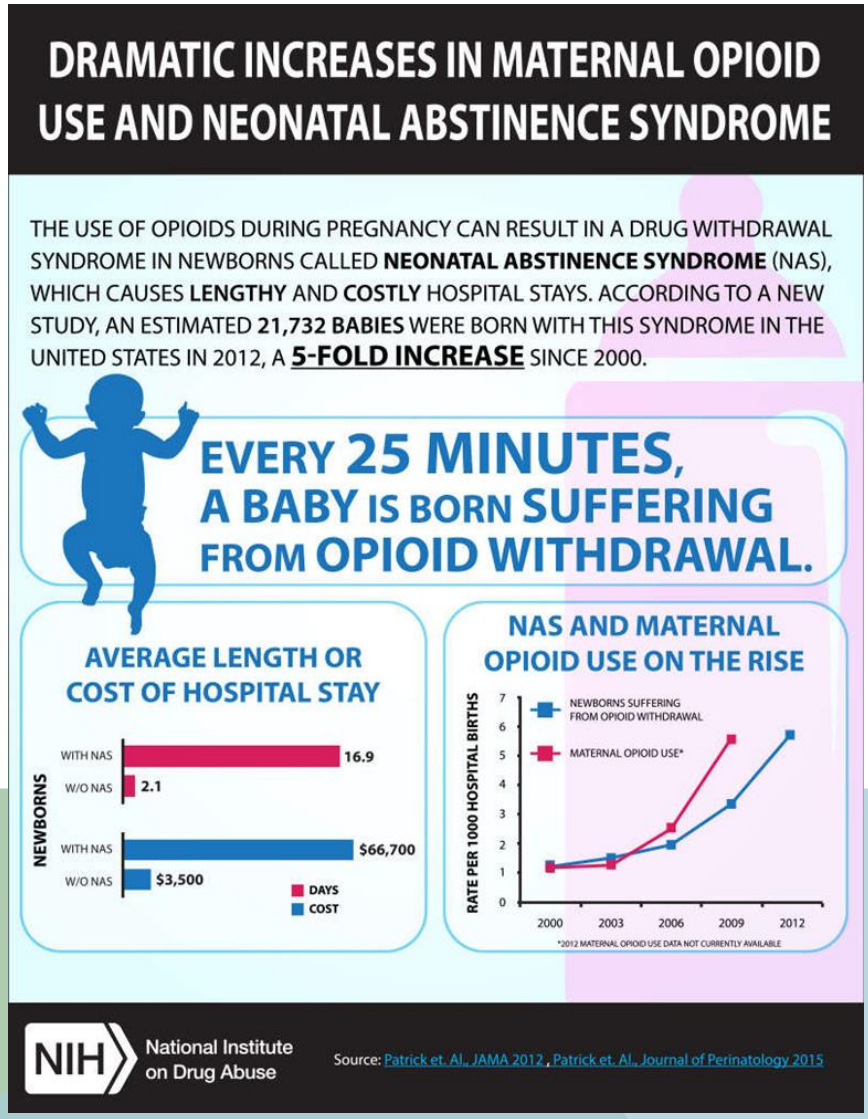
- Suffering is cruel and unnecessary
- Newborns at risk deserve early and effective treatment for opioid withdrawal, just as they do for pain
- The MAiN early treatment model is safe, effective, cost-saving and feasible for hospitals to replicate

GROWING THREAT OF NAS



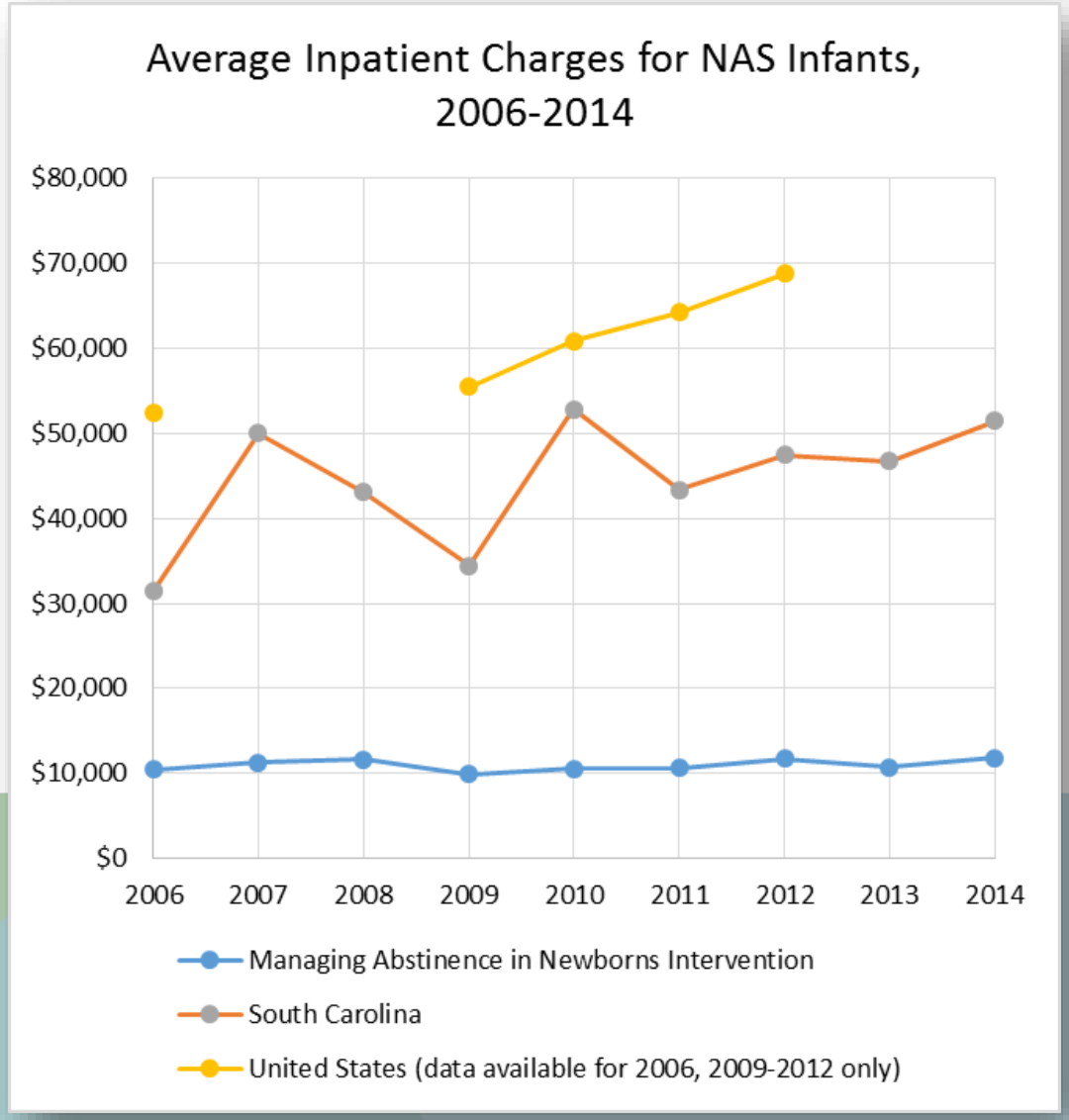
- 30% of young Medicaid women have a current opioid prescription
- Among women using opioids, 86% of pregnancies are unplanned
- Rates of NAS cases from rural communities has risen from 12.9% to 21.2%
- Over 80% of NAS cases are billed to Medicaid

  $1.2 billion in 2012

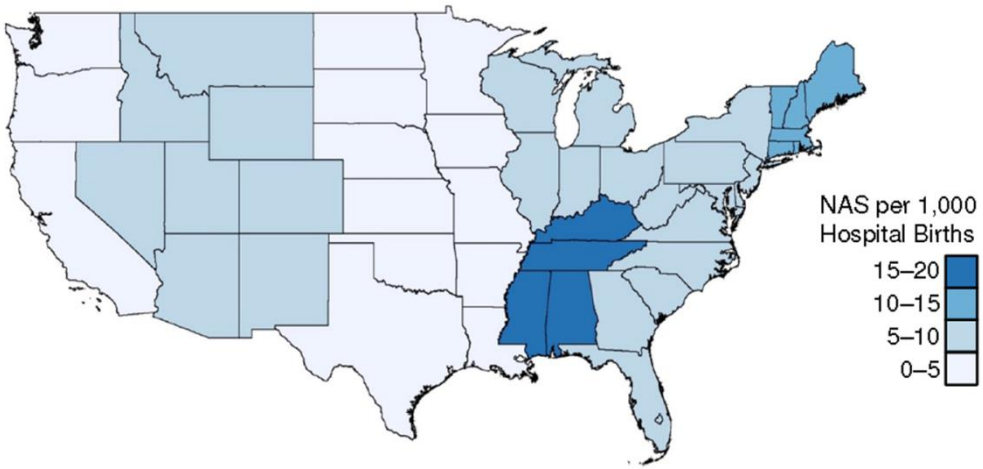
Villapiano NL, et al. JAMA Peds, 2016

Prenatal Drug use and Neonatal Health. US Government Accountability Office, 2015

NAS IN SOUTH CAROLINA



NAS IN SOUTH CAROLINA



Patrick SW, Davis MM, Lehmann CU, et al. *J Perinatol*. 2015 Aug;35(8):650-5

Mean SC Hospital Charges (All Payers) per NAS Birth, 2014	
Overall	$60,176
In NICU	$157,912
Total	$24,250,928

Source of Data:
South Carolina Office of Research and Statistics
Division of Research and Statistics
UB-04 Hospital Billing Data

GROWING THREAT OF NAS

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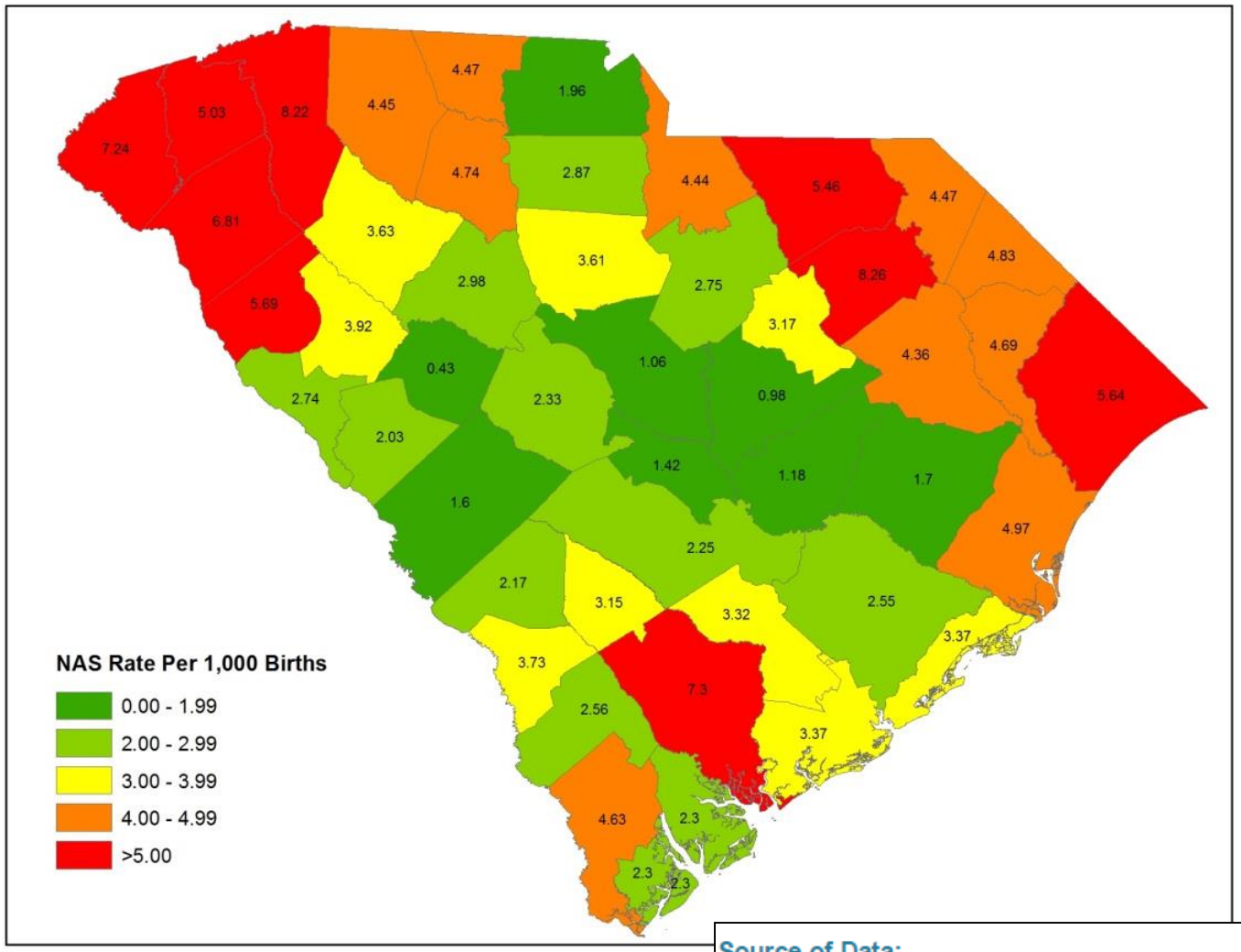
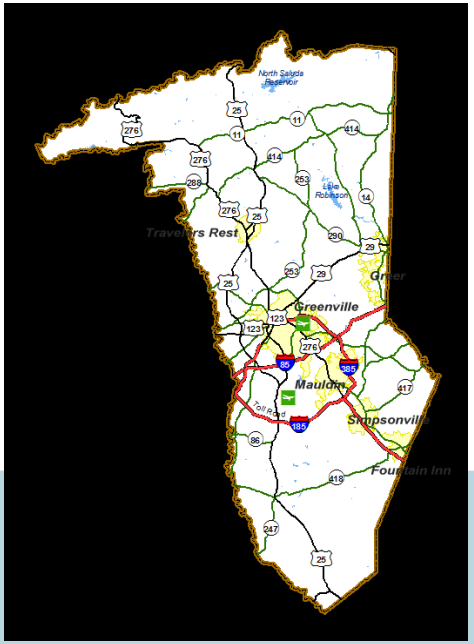
Neonatal Abstinence Syndrome Rate Per 1,000 Births by South Carolina County, 2006-2014



Greenville County
6421 births in 2015
52 potential cases



Source of Data:
South Carolina Office of Research and Statistics

ETHICAL DILEMMAS WITH NEONATAL OPIOID DEPENDENCE

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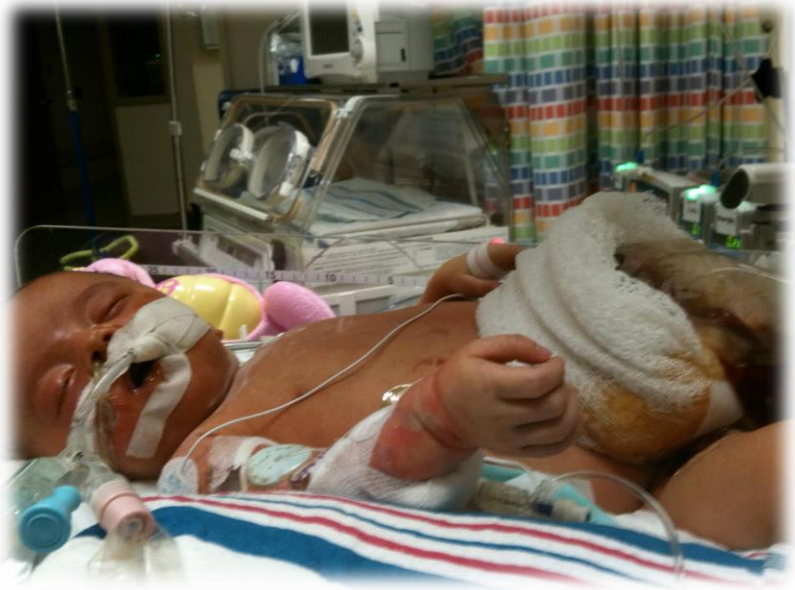

http://faiths-place-08.blogspot.com/2010/06/baby-genevieve.html

Photo used with written consent by newborn's mother for purpose of internal and external education

Pain /pān/

noun

1.physical suffering or discomfort caused by illness or injury

Origin of *PAIN*

Middle English, from Anglo-French *peine*, from Latin *poena*, from Greek *poinē* payment, penalty; akin to Greek *tinein* to pay, *tinesthai* to punish, Avestan *kaēnā* revenge, Sanskrit *cayate* the revenges First Known Use: 14th century

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- Neuroanatomical components and neuroendocrine systems are sufficiently developed to allow transmission of painful stimuli in the neonate.
- Exposure to prolonged or severe pain may increase neonatal morbidity.
- Infants who have experienced pain during the neonatal period respond differently to subsequent painful events.
- Neonates are not easily comforted when analgesia is needed.
- “The prevention of pain in neonates should be the goal of all caregivers…”

Prevention and management of pain and stress in the neonate. AAP Committee on Fetus and Newborn. *Pediatrics*, 2000

Prevention and management of pain in the neonate: an update. AAP Committee on Fetus and Newborn and Section on Surgery, Section on Anesthesiology and Pain Medicine; Canadian Paediatric Society, Fetus and Newborn Committee. *Pediatrics*, 2006

CURRENT CLINICAL CHALLENGES

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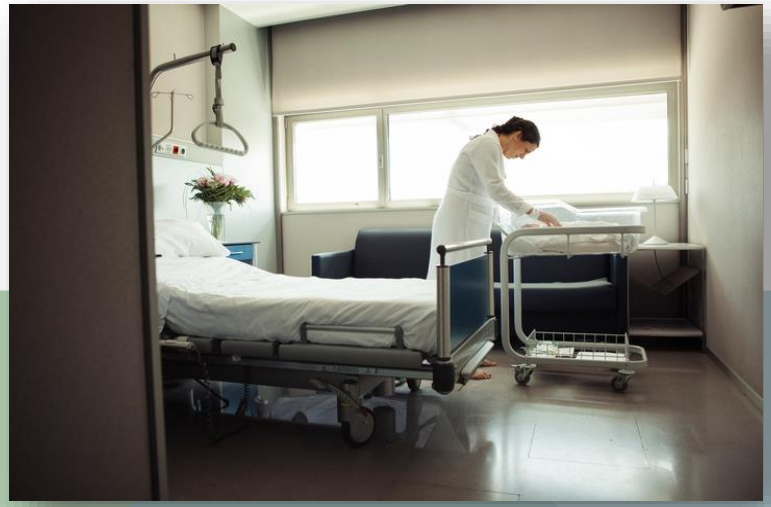
- A majority of birthing centers are not skilled in detecting or treating NAS
- Predicting which babies will develop NAS is difficult
- There is no single recommended approach for NAS care
- Most NAS care currently is delivered in neonatal ICUs



- Separates mother and baby
- Higher length of stay and cost
- ICU beds used for non-critical care

CURRENT CLINICAL CHALLENGES

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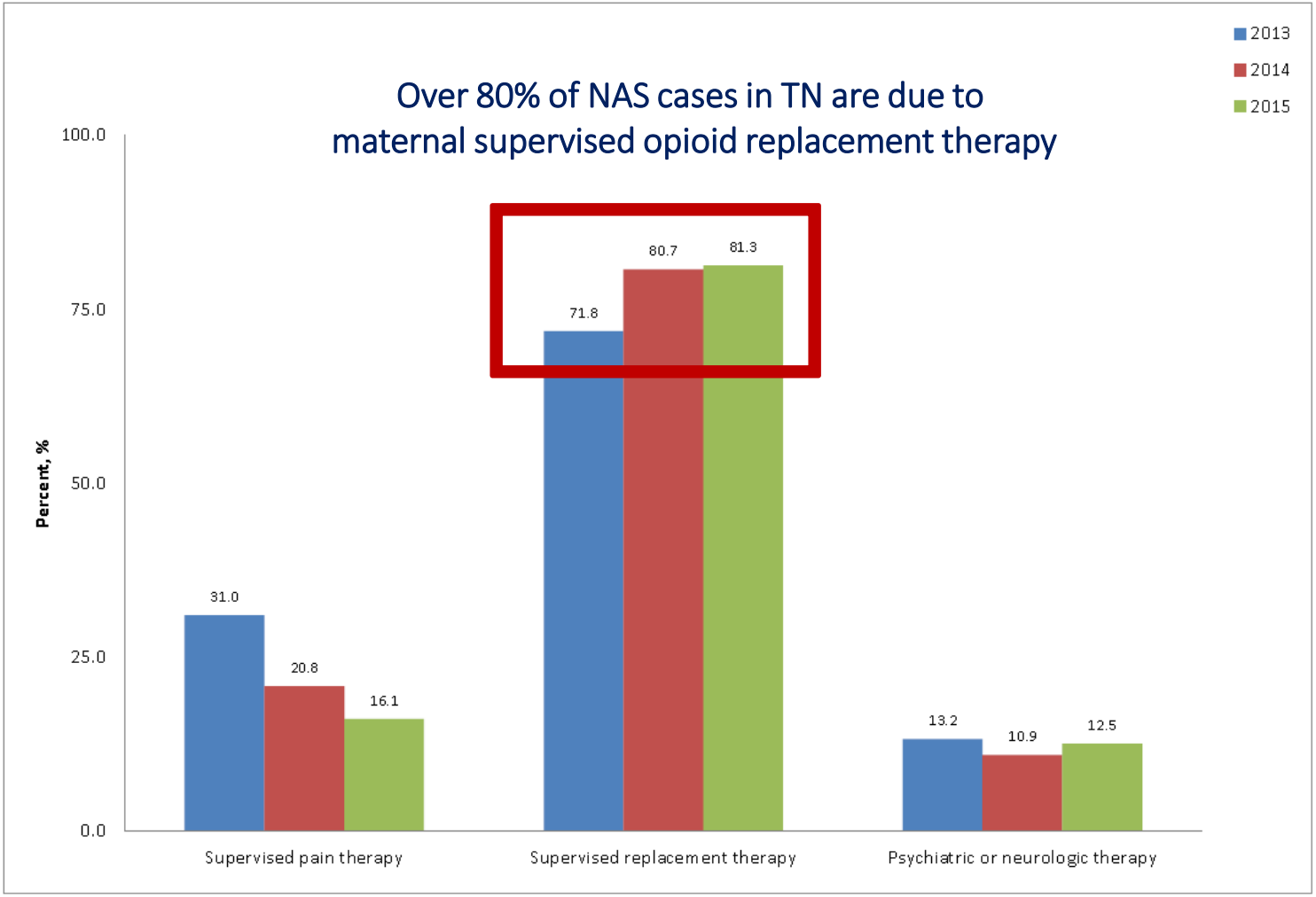

Figure 3: Class of Drug Exposure of Neonatal Abstinence Syndrome Cases with Prescription Drug Exposure Only, Tennessee 2013-2015. Trends were not statistically significant.

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CORE BELIEFS

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- ✓ All women deserve a positive birth experience.
- ✓ Mothers and newborns belong together, with rare exception.
- ✓ Sudden opioid withdrawal is painful, potentially harmful, and should be prevented.
- ✓ Health care providers should advocate for the well-being of vulnerable populations.
- ✓ All patients deserve a primary care medical home.

GUIDING PRINCIPLES

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- A majority of NAS cases are associated with maternal supervised opioid replacement therapy.
- Otherwise healthy newborns chronically exposed to long-acting opioids in late gestation may be presumed opioid-dependent and at high risk for withdrawal.
- Opioid-dependent newborns, whether due to fetal or postnatal exposure, should be managed using similar methods, such as anticipatory oral weaning.
- Ongoing NAS care in NICUs will increasingly strain resources needed for other critical neonatal conditions.
- Prolonged hospitalization is associated with high costs and rare but serious safety risks.
- Rooming-in promotes maternal-infant bonding and a supportive care environment for treating NAS.
- Case management services to develop appropriate plans of safe care are especially beneficial for mothers with substance use disorders and their infants.

CRITICAL COMPONENTS

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Early Medication Treatment for Qualified Newborns

(within 24 hours of birth)

Rooming-in with Mother or Care in Level I Nursery

Inpatient Stabilization with Outpatient Wean

(average LOS 8 days)

OUTPATIENT CARE

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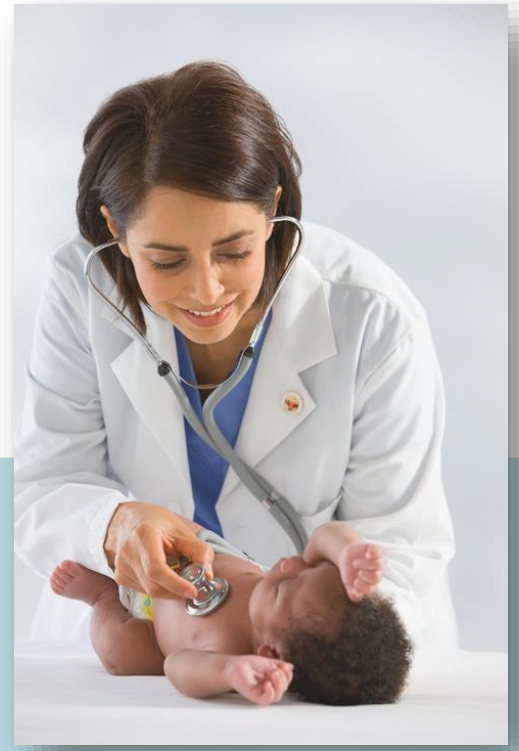
Weaning Calendar with Pre-Filled Oral Syringes

Outpatient Check-Ups Weekly for 4 Weeks



SC DHEC Nurse Home Visit(s)

MEASURING OUTCOMES

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Retrospective study of eligible babies born at GHS with NAS diagnosis from 2006-2014 conducted by Clemson University to:

- **Describe** the health outcomes and hospital costs for newborns with NAS who were treated with MAiN
- **Forecast** the potential long-term Medicaid savings due to wider implementation of MAiN
- **Compare** outcomes of MAiN infants to comparable NAS infants receiving traditional care between 2006-2014 in SC

Newborn Demographics (N= 117)	
Male Gender	59 (50%)
Caucasian Race	105 (90%)
Gestational Age 35-36 weeks 37 weeks 38-42 weeks	 12 (10%) 23 (20%) 80 (70%)
Apgar Score at 5 Minutes ≥ 8	115 (98%)
Small for Gestational Age	20 (17%)
Insured by Medicaid	111 (95%)

CLEMSON UNIVERSITY

MEDICAL OUTCOMES

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Medical Outcomes (n=117)	
Median peak modified Finnegan score	10 (mean peak DOL 2)
Average peak weight loss level (%)	7 ± 2.5% (mean peak DOL 3)
Prominent GI symptoms (vomiting, diarrhea, poor feeding)	7%
Prominent CNS symptoms (crying, wakeful, tremors, hypertonic, hyperreflexic)	51%
Over-sedation from medication	4%
Safety events Unsafe sleeping Infant fall/drop Near suffocation Medication error by hospital staff Death	 7% 1% 2% 0 0
ER visit after discharge (30 days) Readmitted (RSV, pertussis, fever, vomiting, failure to thrive)	14% 7%

CLINICAL OUTCOMES

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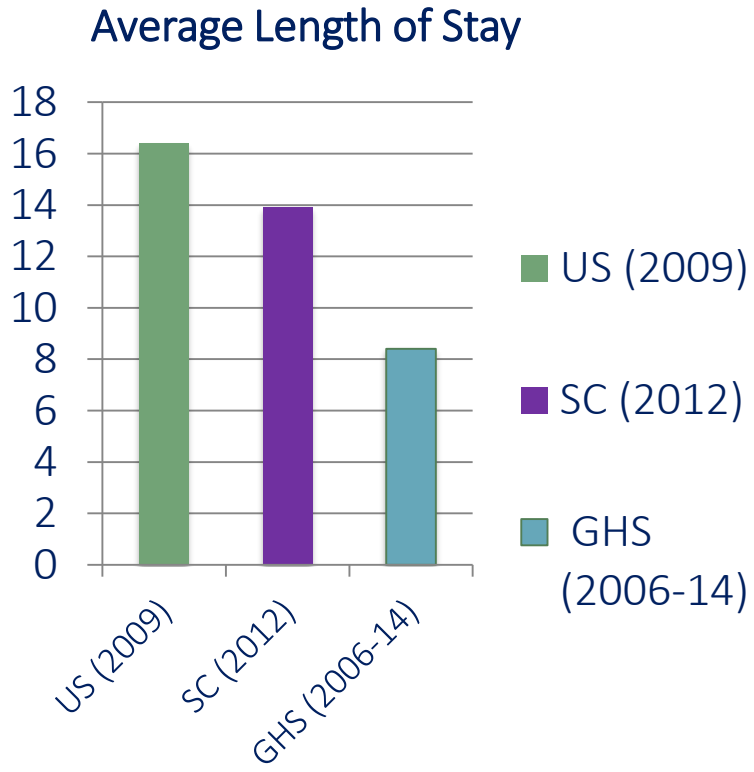
Medication Treatment Variables (n=117)	
Average discharge methadone dose	0.5 ± 0.25 mg/kg/day 0.6 mg every 12 hours
Mean amount of methadone dispensed	33 mg

Current cost to family for infant's weaning medication: $4-12

COSTS & UTILIZATION



MAiN-Treated Newborns (n=117)	Mean
Hospital **charges** per case	$10,945
Hospital **reimbursement** per case	$5,261
Hospital **costs** per case	$5,909
Length of stay, days	8.3

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MAIN EXPANSION

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- Implementation at AnMed since 2016
- Preliminary Analyses indicate that MAiN patients at AnMed experienced similar outcomes to the patients historically treated at GHS, including:

  - Mean length of stay: 8.3 days
  - Mean rooming-in days: 3.4 days
  - Mean peak weight loss: 4.7%
  - Mean peak Finnegan score: 7
  - Breastfeeding rate: 33%

AnMed Health
We're in this together.

MAIN EXPANSION

AnMED Health
We're in this together.

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Implementation Successes

- *Consistent care*
- *Seeing results immediately*
- *New resources (OT, monitors)*
- *Mentoring and support*

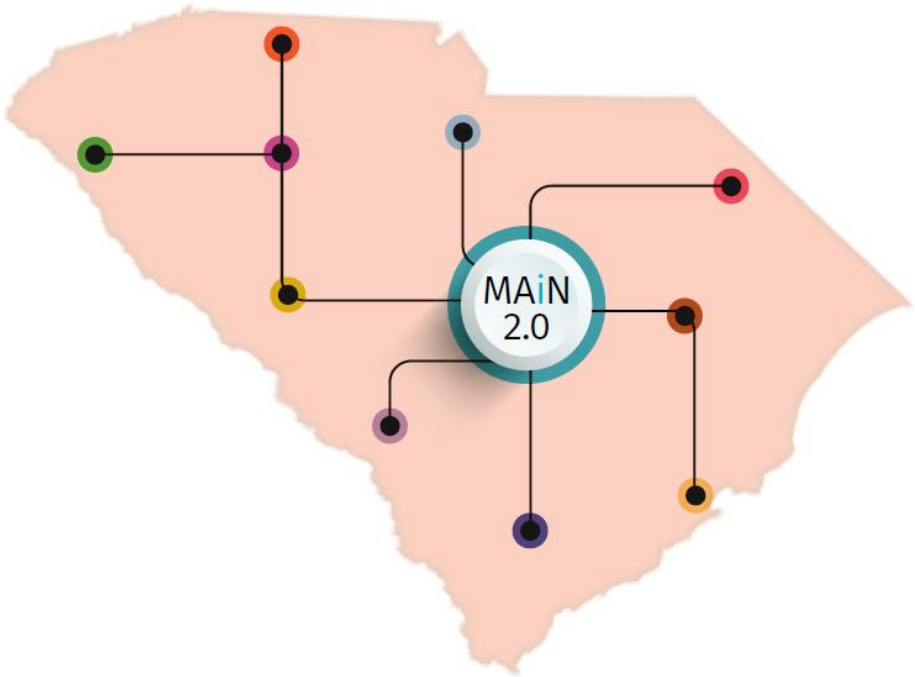
Ann Patterson, MD, Pediatric Hospitalist
"Anytime I've had questions about anything, I have been supported. In the beginning, when there were questions about forms, I was able to ask Dr. Hudson and get to her quickly. MAiN staff members have always gotten back to me and been very responsive. "

Implementation Barriers

- *Monitoring equipment and workflow issues*
- *Talking to families about early treatment*
- *Staff resistance to change*
- *Training needs*

Doris Street, BS, BSN, RN, CNOR, NE-BC, Nurse Manager, Maternity Services
"The MAiN model was successful because our patients really loved the fact that they would be able to stay here with their baby. Also, it was easier to have the early intervention, it made it easier for the staff, doctors, and patients."

MAIN EXPANSION



The MAiN Program administrators, with support from the South Carolina Department of Health and Human Services, will partner with 10 birthing hospitals across SC over the next four years to implement the MAiN model at their facilities.

BECOME A PARTNER

Applications Open Tomorrow
Available on Website www.mainbabies.org
Two-Part Application is due by December 20

Application Instructions

Hospitals that wish to be considered as a MAiN expansion site must follow the application process:

Step 1: Complete the self-appraisal and written application and obtain required signatures.

Step 2: Return the fully completed, signed application and self-appraisal to the MAiN Program Manager via email to mgreco@ghs.org or via fax at 864-455-4241 by close of business on the **deadline of December 20, 2017.**

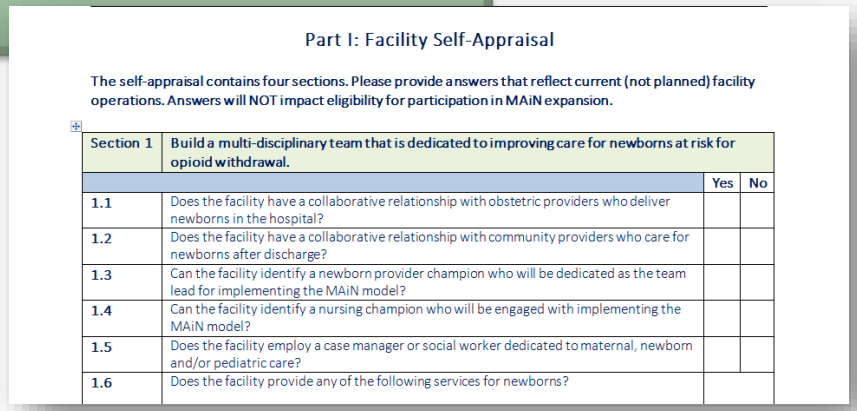
Step 3: Have patience! Depending on the number applications received, we may contact you in January to request a teleconference or additional information. You will be notified of the status of your application in early February.

Step 4: Share the love! To show our love for our new partners, the first round of selected participants will be announced at the South Carolina Birth Outcomes Initiative meeting at the South Carolina Hospital Association in Columbia on Valentine's Day (February 14) 2018! Applicants are invited and encouraged to attend the meeting.

APPLICATION PROCESS

Managing Abstinence in Newborns

Part I: Self-Appraisal



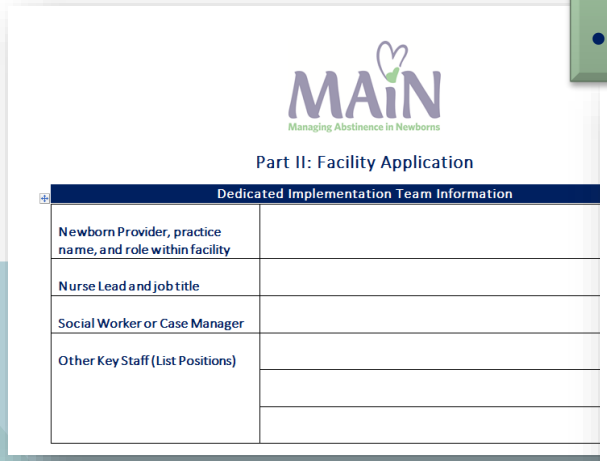
Part I: Facility Self-Appraisal

The self-appraisal contains four sections. Please provide answers that reflect current (not planned) facility operations. Answers will NOT impact eligibility for participation in MAiN expansion.

Section 1	Build a multi-disciplinary team that is dedicated to improving care for newborns at risk for opioid withdrawal.		
		Yes	No
1.1	Does the facility have a collaborative relationship with obstetric providers who deliver newborns in the hospital?		
1.2	Does the facility have a collaborative relationship with community providers who care for newborns after discharge?		
1.3	Can the facility identify a newborn provider champion who will be dedicated as the team lead for implementing the MAiN model?		
1.4	Can the facility identify a nursing champion who will be engaged with implementing the MAiN model?		
1.5	Does the facility employ a case manager or social worker dedicated to maternal, newborn and/or pediatric care?		
1.6	Does the facility provide any of the following services for newborns?		

Part II: Application

- Identify a dedicated Implementation Team
- Provide Facility Data
- Answer Narrative Questions



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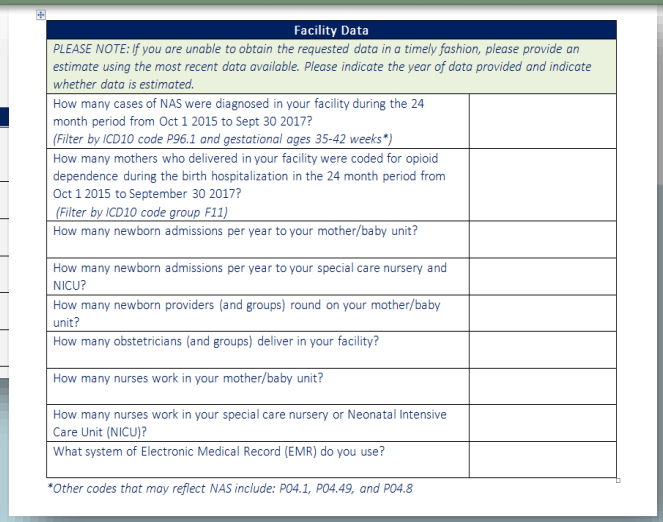
Part II: Facility Application

Dedicated Implementation Team Information	
Newborn Provider, practice name, and role within facility	
Nurse Lead and job title	
Social Worker or Case Manager	
Other Key Staff (List Positions)	



Facility Data	
PLEASE NOTE: If you are unable to obtain the requested data in a timely fashion, please provide an estimate using the most recent data available. Please indicate the year of data provided and indicate whether data is estimated.	
How many cases of NAS were diagnosed in your facility during the 24 month period from Oct 1 2015 to Sept 30 2017? *(Filter by ICD10 code P96.1 and gestational ages 35-42 weeks*)*	
How many mothers who delivered in your facility were coded for opioid dependence during the birth hospitalization in the 24 month period from Oct 1 2015 to September 30 2017? *(Filter by ICD10 code group F11)*	
How many newborn admissions per year to your mother/baby unit?	
How many newborn admissions per year to your special care nursery and NICU?	
How many newborn providers (and groups) round on your mother/baby unit?	
How many obstetricians (and groups) deliver in your facility?	
How many nurses work in your mother/baby unit?	
How many nurses work in your special care nursery or Neonatal Intensive Care Unit (NICU)?	
What system of Electronic Medical Record (EMR) do you use?	

**Other codes that may reflect NAS include: P04.1, P04.49, and P04.8*

APPLICATION PROCESS

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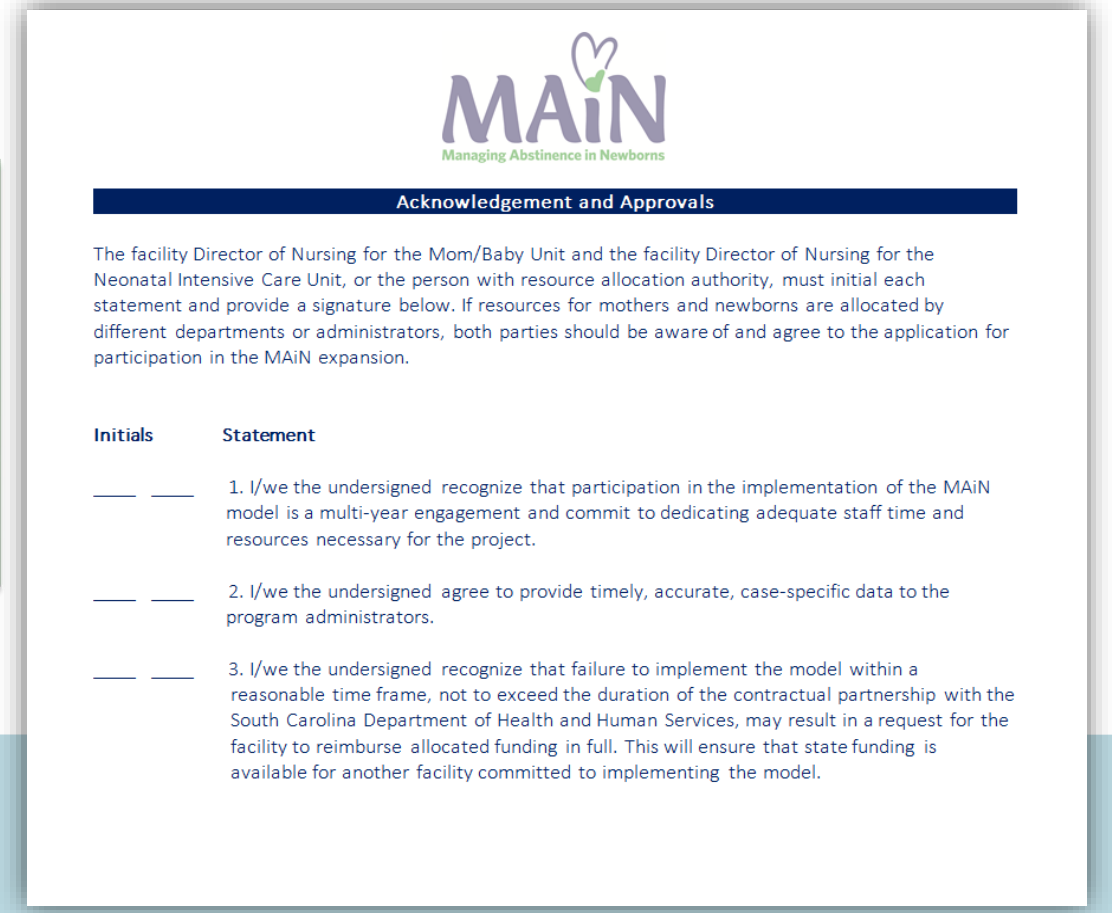
Acknowledgement and Signatures:

- ✓ Agree to dedicate time and staff resources
- ✓ Agree to provide data
- ✓ Understand funding agreement



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Acknowledgement and Approvals

The facility Director of Nursing for the Mom/Baby Unit and the facility Director of Nursing for the Neonatal Intensive Care Unit, or the person with resource allocation authority, must initial each statement and provide a signature below. If resources for mothers and newborns are allocated by different departments or administrators, both parties should be aware of and agree to the application for participation in the MAiN expansion.

Initials	Statement
____ ____	1. I/we the undersigned recognize that participation in the implementation of the MAiN model is a multi-year engagement and commit to dedicating adequate staff time and resources necessary for the project.
____ ____	2. I/we the undersigned agree to provide timely, accurate, case-specific data to the program administrators.
____ ____	3. I/we the undersigned recognize that failure to implement the model within a reasonable time frame, not to exceed the duration of the contractual partnership with the South Carolina Department of Health and Human Services, may result in a request for the facility to reimburse allocated funding in full. This will ensure that state funding is available for another facility committed to implementing the model.

PHASES OF PROJECT PARTNERSHIP

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MAiN*framing*

3 months

- Review materials on www.mainbabies.org
- Identify your dedicated MAiN team
- Complete and submit applications on or before December 20
- Attend BOI monthly meeting on February 14, 2018 for announcement

MAiN*streaming*

3-4 months

- Host the MAiN Program administrators for a site visit to your facility
- Conduct review of current processes related to NAS care
- Develop a detailed action plan for implementation
- Complete online training
- Access and use MAiN model development tools on website

MAiN*taining*

1-3 years

- Implement necessary policy or procedural changes
- Launch MAiN at your facility with onsite training
- Receive support from MAiN Program administrators monthly and as needed
- Report case data to MAiN Program administrators upon infant discharge from hospital

PROJECT PARTNERSHIP

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Partner Hospitals Will Receive:

- On-site Training
- Access to online training tools and resources
- Remote support during model implementation
- Funding to offset implementation costs

Ideal Partner Hospital Profile:

- Level II – IV designations
- High delivery rates (~500/year)
- High case rates of NAS babies and/or mothers on opioid replacement therapy

Partner Hospitals Agree to:

- Dedicate adequate staff time and resources necessary to implement the model
- Provide timely, accurate, and case-specific data to the program administrators

STAKEHOLDERS

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- DAODAS, SCATOD, opioid treatment providers
- Medicaid managed care organizations
- DHEC, WIC, SCRIPTS
- DSS, Community-Based Prevention Services
- Behavioral and Mental Health Services
- Hospital staff
- Statewide community support services
- Primary care providers for pregnant women and children
- Affected families
- SC legislators

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QUESTIONS

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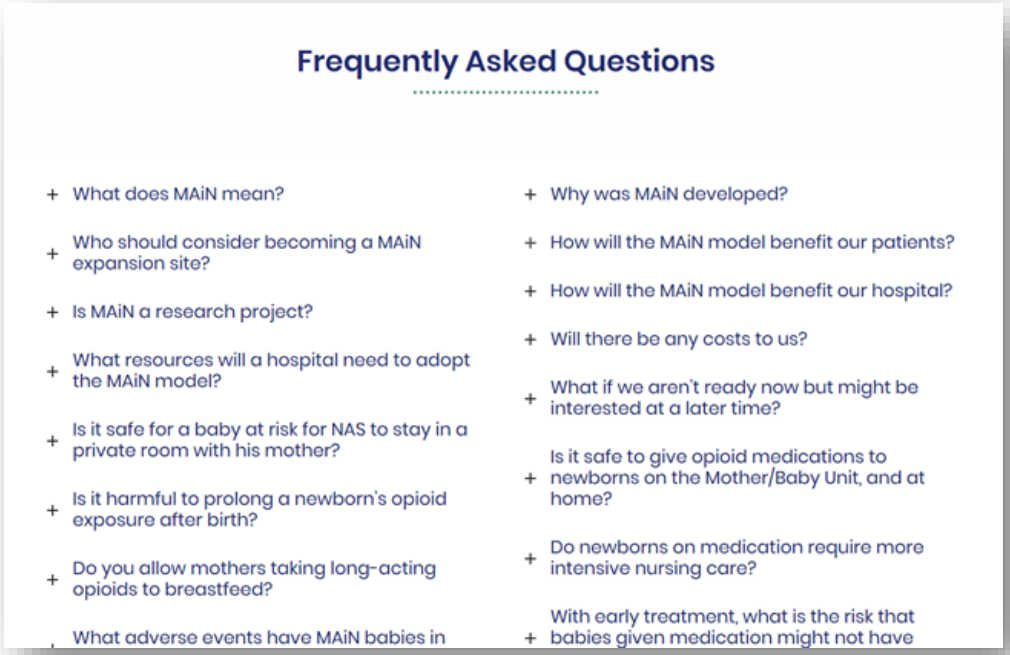
Research
Resources needed
Medical home
DSS involvement
Benefits to patients and hospital
More…



Frequently Asked Questions

+ What does MAiN mean?
+ Who should consider becoming a MAiN expansion site?
+ Is MAiN a research project?
+ What resources will a hospital need to adopt the MAiN model?
+ Is it safe for a baby at risk for NAS to stay in a private room with his mother?
+ Is it harmful to prolong a newborn's opioid exposure after birth?
+ Do you allow mothers taking long-acting opioids to breastfeed?
+ What adverse events have MAiN babies in
+ Why was MAiN developed?
+ How will the MAiN model benefit our patients?
+ How will the MAiN model benefit our hospital?
+ Will there be any costs to us?
+ What if we aren't ready now but might be interested at a later time?
+ Is it safe to give opioid medications to newborns on the Mother/Baby Unit, and at home?
+ Do newborns on medication require more intensive nursing care?
+ With early treatment, what is the risk that babies given medication might not have

CONTACT US

MAiN
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Website: mainbabies.org

Phone: 864-455-3114

Fax: 864-455-4241

Email: mgreco@ghs.org
jhudson@ghs.org

Research questions?
rmayo@clemson.edu